

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
1 May 2003 (01.05.2003)

PCT

(10) International Publication Number
WO 03/034941 A1

(51) International Patent Classification⁷: **A61F 2/01**

(21) International Application Number: **PCT/US02/30114**

(22) International Filing Date:
23 September 2002 (23.09.2002)

(25) Filing Language: **English**

(26) Publication Language: **English**

(30) Priority Data:
10/045,628 19 October 2001 (19.10.2001) **US**

(71) Applicant: **SCIMED LIFE SYSTEMS, INC.** [US/US];
One SciMed Place, Maple Grove, MN 55311 (**).

(72) Inventors: **SALAHIEH, Amr**; 18729 Metler Court,
Saratoga, CA 95070 (US). **DEMOND, Jackson**; 149
Plateau Avenue, Santa Cruz, CA 95060 (US). **KROLIK,**
Jeff; 120 North Third Street, Campbell, CA 95008 (US).

(74) Agents: **SEAGER, Glenn, M.** et al.; Crompton, Seager
& Tufte, LLC, Suite 895, 331 Second Avenue South, Min-
neapolis, MN 55401-2246 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG,
SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN,
YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK,
TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).

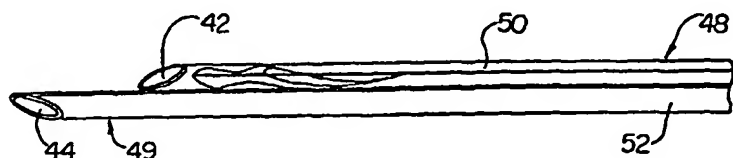
Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

WO 03/034941 A1

(54) Title: **VASCULAR EMBOLIC FILTER EXCHANGE DEVICES**



(57) Abstract: Vascular embolic filter-
ing systems, as well as methods for us-
ing the same, are provided. In general,
the subject invention includes a system
comprised of an embolic filter assembly
and a multiple lumen delivery and re-
trieval sheath, where the embolic filter
assembly includes a guide wire with an

embolic filter operatively coupled to the distal end of the guide wire for capturing emboli created during interventional procedures within a target vessel. Features of the subject invention provide for the rapid exchange and deployment of embolic filters in a patient's vasculature.

VASCULAR EMBOLIC FILTER EXCHANGE DEVICES

INTRODUCTIONField of the Invention

The present invention relates to systems and methods for filtering and removing matter from within the vasculature. More particularly, the invention is directed to the intravascular exchange of intravascular devices useful for capturing emboli generated during interventional procedures, and for thrombectomy and embolectomy procedures.

Background of the Invention

Vascular procedures to treat occlusive vascular diseases, such as angioplasty, atherectomy and stent placement, often cause blood clots to form and/or material to dislodge from inside the vessel walls and enter the bloodstream. The dislodged material (e.g., plaque), known as emboli, may be large enough to occlude smaller downstream vessels, potentially blocking blood flow to tissue. Additionally, the blood clots, known as thrombi, may be large enough or grow over time to form a blockage at the interventional site or at another downstream location should the thrombus become released into the bloodstream.

There are numerous previously known interventional systems and methods that employ a filter mechanism designed to capture material liberated from vessel walls during the treatment or diagnosis of vascular disease. Many of the more recent devices employ radially expandable filters disposed at the distal end of a guide wire. These filters have various configurations, such as mesh or microporous membranes in the form of sleeves, parachutes or baskets attached to the guide wire or other delivery mechanism by means of struts, wires, ribs or frames. The meshes are frequently made of woven or braided fibers or wires made of stainless steel, nitinol, platinum alloy, polyester, nylon or porous plastics, for example. The microporous membranes are typically made of a polymer material such as polypropylene, polyurethane, polyester, polyethylene tetrathalate, polytetrafluoroethylene or combinations thereof.

Examples of procedures employing such filters include angioplasty, atherectomy, thrombectomy and stent placement. These procedures typically involve

transluminally inserting and delivering within a vessel, a guide wire with an attached filter to a location distal to a lesion or treatment site, and deploying the filter. The interventional device is then delivered over the guide wire to the treatment site. During the treatment of a lesion within the patient's vessel, plaque is often liberated from the walls of the vessel creating emboli within the bloodstream. These emboli are then captured within the deployed filter, where they remain for the duration of the treatment procedure.

Depending on the amount of plaque dislodged from the vessel wall, the embolic filter may become occluded with emboli during an interventional procedure, thus preventing blood from flowing through the filter. As a result, a pool forms proximal to the filter. When the filter becomes full or occluded with emboli and debris, the interventional procedure may need to be terminated so that the filter can be removed from the vasculature. As such, the duration of the interventional procedure is dependent upon the emboli-filling capacity of the deployed filter.

Numerous approaches have been postulated to overcome the increased procedure times associated with the retrieval and subsequent exchange of emboli-laden filters from a patient's vasculature. For example, one such approach is to employ an aspiration device to aspirate emboli contained within a filter sac of a vascular filter, so as to eliminate the need to retrieve and exchange the filter when it becomes full of emboli. However, there are significant disadvantages associated with this approach, including increased procedural complexity, the need for additional components and the inability to completely aspirate emboli entrapped in the filter pores.

In view of the description of the foregoing devices and methods, it is desirable to provide an improved embolic filter system. Additionally, it is desirable to have such systems that provide for the rapid exchange of embolic filters during the course of an interventional diagnostic or therapeutic procedure and/or in which a stent is deployed. Further, it is advantageous to have such systems capable of delivering multiple filters and/or interventional devices without losing guide wire access to the target site. In addition, it is desirable that there be a safe withdrawal of the deployed embolic filters from the vasculature. It is also desirable to first insert a guide wire distal the target region, and then subsequently replace the guide wire with a filter wire

attached to a filter. Insertion of a guide wire first, and then subsequently replacing the guide wire with a filter and filter wire, enables the clinician to more accurately maneuver the embolic filter across the site of the lesion.

SUMMARY OF THE INVENTION

The present invention pertains to embolic protection systems deployed in a body vessel or cavity for the collection of loosened and/or dislodged debris, such as embolic material dislodged during, or thrombi formed as a result of, an interventional procedure. The present invention is particularly helpful to protect the vasculature of a patient from dislodged emboli during interventional procedures such as angioplasty, atherectomy, thrombectomy, embolectomy, intravascular diagnostic and stent placement procedures by enabling rapid exchange of embolic filters during the course of the interventional procedure.

Vascular embolic filter systems, as well as methods for using the same, are provided. In one particular embodiment, the subject invention includes a system comprised of an embolic filter assembly and a multiple lumen delivery and retrieval sheath, where the embolic filter assembly includes a guide wire with an embolic filter operatively coupled to the guide wire for capturing emboli created during interventional procedures within a target vessel. Features of the subject systems provide for the rapid exchange and deployment of embolic filters in a patient's vasculature. Rapid exchange of embolic filters during the course of a procedure decreases overall procedure times and minimizes the risks associated with occluded embolic filters.

Specifically, the rapid exchange of embolic filters is accomplished by sequentially retrieving an occluded filter and deploying a second, unused or unoccluded filter through a single delivery and retrieval sheath having at least two lumens, without having to remove the occluded filter and/or the sheath prior to delivering and deploying the second filter.

As such, a first embolic filter is deployed to a target site distal to a stenosis such that the first deployed embolic filter creates an opening or mouth through which emboli and debris can flow. Once a first embolic filter is deployed, an interventional device can be advanced to the site of the stenosis and the interventional procedure

may commence. Once filled with emboli and debris, the interventional device is removed from the vessel. The multiple lumen delivery and retrieval sheath of the present invention is then advanced over the guide wire in order to retrieve the first embolic filter and to deliver and deploy a second embolic filter. The guide wire with the first embolic filter attached is pulled or retracted into the first lumen of the sheath, or alternatively the sheath is advanced over the guide wire and attached embolic filter, causing the filter opening or mouth to close or collapse. Such withdrawal prevents emboli collected during the procedure from escaping into the patient's blood. Once the first embolic filter is effectively withdrawn into a lumen of the delivery and retrieval sheath so as to prevent the escape of collected emboli, a second embolic filter can be deployed to the target site through a second lumen of the delivery and retrieval sheath. Again, when filled with emboli and debris, the second deployed embolic filter can also be retrieved by withdrawing it at least partially into a second lumen of the delivery and retrieval sheath in order to sufficiently close or collapse the filter mouth to prevent the escape of emboli from the embolic filter. Additional filters can also be rapidly advanced, deployed and retrieved as described above, in certain embodiments through additional lumens within the multiple lumen delivery and retrieval sheath.

In another embodiment of the present invention, an interventional device such as an angioplasty catheter, embolectomy device, atherectomy device or the like is advanced to the procedure site through one of the lumens of the multiple lumen delivery and retrieval sheath of the present invention. In certain embodiments, embolic filter exchange and the interventional procedure can occur without the need to remove the sheath from the vasculature between exchanges, thus further reducing procedure times.

In yet another embodiment of the present invention, a guide wire shaft defining a guide wire lumen is operatively coupled to a filter wire. The guide wire shaft, along with the filter wire, can be advanced along a guide wire to point distal a lesion. Once the guide wire shaft is in place, the guide wire can be removed, and a filter sheath containing a filter assembly disposed about the filter wire can be retracted to deploy an embolic filter within the vessel. Once occluded, the embolic filter can be

again collapsed by sliding the filter sheath over the filter assembly, and then withdrawn from the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates an embolic filter suitable for use with the present invention.

Figure 2 includes Figures 2A & 2B which illustrate different embodiments of a delivery and retrieval sheath of the present invention; wherein:

Figure 2A illustrates one embodiment of a delivery and retrieval sheath of the present invention having at least two lumens and having an embolic filter system disposed therein; and

Figure 2B illustrates another embodiment of a delivery and retrieval sheath of the present invention having lumens of differing lengths;

Figure 3 includes Figures 3A-F which illustrate an embolic filter system of the present invention and a method for using same; wherein:

Figure 3A illustrates the multiple lumen delivery and retrieval sheath of Figure 2A with a first embolic filter of the present invention operatively coupled to a first guide wire and disposed in an undeployed, pre-delivery state within a first lumen of the sheath;

Figure 3B illustrates the first embolic filter of Figure 3A, now fully deployed inside a vessel at a location distal to a stenotic lesion;

Figure 3C illustrates the first embolic filter of Figure 3B, substantially filled with emboli, and the multiple lumen delivery and retrieval sheath of Figure 2A advanced to retrieve the deployed first filter and to deploy a second filter disposed within a second lumen of the multiple lumen delivery and retrieval sheath;

Figure 3D illustrates the retrieval of the first embolic filter into the first lumen of the multiple lumen delivery and retrieval sheath;

Figure 3E illustrates the deployment of the second embolic filter into the vessel with the first embolic filter at least partially withdrawn into the first lumen of the multiple lumen delivery and retrieval sheath; and

Figure 3F illustrates the second embolic filter fully deployed within the vessel at a location distal to the stenotic region.

Figure 4 includes Figures 4A-4D which illustrate a filter exchange system in accordance with another embodiment of the present invention; wherein:

Figure 4A illustrates a guide wire inserted into a vessel at a location distal to a stenotic region.

Figure 4B illustrates a filter exchange system having a guide wire shaft, a guide wire lumen, a filter and a filter lumen advanced to a distal portion of the guide wire shown in Fig. 4A;

Figure 4C illustrates the filter exchange system of Figure 4B, wherein the guide wire has been withdrawn; and

Figure 4D illustrates the embolic filter in the filter exchange system of Figure 4B in a fully deployed state at a location distal to the stenotic region.

Figure 5 includes Figures 5A – 5E which illustrate a filter exchange system in accordance with yet another embodiment of the present invention; wherein:

Figure 5A illustrates an exchange sheath disposed over a guide wire and having a filter assembly disposed within the sheath;

Figure 5B illustrates the exchange sheath of Figure 5A wherein the guide wire has been withdrawn;

Figure 5C illustrates the filter assembly of Figure 5B wherein the exchange sheath has been withdrawn;

Figure 5D illustrates the advancement of an exchange sheath and guide wire over the filter assembly of Figure 5C;

Figure 5E illustrates the exchange sheath of Figure 5D advanced over the filter assembly of Figure 5C.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

RAPID EXCHANGE EMBOLIC FILTER SYSTEM

EMBOLIC FILTER ASSEMBLY

An embolic filter assembly of the present invention is comprised of an embolic filter operatively coupled to a guide wire. A number of embolic filters are known for providing distal protection against embolization in conjunction with a transluminal diagnostic or therapeutic procedure, such as angioplasty or embolectomy. These embolic filters are deployed distal to a vascular lesion, such as a

stenosis, prior to undertaking the diagnostic or therapeutic procedure, and are designed to collect emboli liberated during the procedure to prevent them from entering the blood stream. Generally, embolic filters suitable for use with the present invention are characterized by having a blood permeable sac and a support hoop which forms an opening into the sac; however, other types of filters are also useable with the present invention.

Referring now to Figure 1, a schematic of an embolic filter assembly suitable for use with the present invention is shown deployed within vessel V distal a lesion. Embolic filter assembly 29 includes embolic filter 30 and guide wire 38. Embolic filter 30 includes self-expanding support hoop 31, preferably mounted on suspension strut 32, which supports blood permeable sac 33. As such, support hoop 31 forms a mouth or proximal opening of sac 33 while blood permeable sac 33 provides a closed, but permeable distal end 36. Support hoop 31 is preferably formed of a super-elastic material, such as nitinol, and has a constrictable, preformed shape. Accordingly, support hoop 31 is collapsible to fit into a delivery and retrieval sheath, and then expandable to its preformed shape. Suspension strut 32 is attached to guide wire 38 at joint 34 by means of a solder bead or shrink tubing, for example.

Blood permeable sac 33 is preferably made of a material having a multiplicity of pores. Suitable materials include, but are not limited to, biocompatible polymeric materials such as polyethylene, polypropylene, polyurethane, polyester, polyethylene tetrathalate, nylon, polytetrafluoroethylene, or combinations thereof. These pores, in turn, permit red blood cells to pass through the sac substantially unhindered, while capturing and retaining larger emboli and debris that may be released during an interventional procedure.

As described, blood permeable sac 33 is preferably comprised of a suspension strut 32 or other support means to hold support hoop 31 substantially concentric to guide wire 38, thereby allowing guide wire 38 to bend and move laterally without lifting support hoop 31 from the wall. Accordingly, suspension strut 32 advantageously permits support hoop 31 to become concentrically displaced relative to guide wire 38 when embolic filter 30 is deployed in a curved vessel.

DELIVERY AND RETRIEVAL SHEATHS

As indicated above, an embolic filter assembly, e.g., embolic filter 30 operatively coupled to guide wire 38, is advanced to a target site within a vessel through a delivery and retrieval sheath. The delivery and retrieval sheath of the present invention, in turn, is used to advance, deliver, deploy and retrieve an embolic filter assembly to a target location within a vessel. In one embodiment of the present invention, the delivery and retrieval sheath includes two lumens for rapid delivery and retrieval of filter assemblies. In yet another embodiment of the present invention, the delivery and retrieval sheath includes three or more lumens for deployment and retrieval of additional filter assemblies, interventional therapeutic devices, diagnostic devices and/or stents. Each lumen has a proximal opening, and a distal opening.

Referring to Figures 2A-B, various embodiments of delivery and retrieval sheaths suitable for use with the present invention will now be described. Delivery and retrieval sheath 40, shown in Figure 2A includes a proximal end 48, a distal end 49 and two lumens 50 and 52 having distal openings 42 and 44 respectively. Lumens 50 and 52 share a common wall 46. In this particular embodiment, the distal ends of lumens 50 and 52 terminate at substantially the same point, i.e., the distal opening 42 of lumen 50 and distal opening 44 of lumen 52 are substantially even. Delivery and retrieval sheath 40 is shown with an embolic filter assembly therein, such as the embolic filter assembly 29 shown in Figure 1. Accordingly, embolic filter 30 is in a folded or constricted or undeployed, pre-delivery state disposed within a first lumen 50 of delivery and retrieval sheath 40.

Figure 2B shows an alternative embodiment of the delivery and retrieval sheath of Figure 2A. In this particular embodiment, the distal end of lumen 50 terminates proximally of the distal end of lumen 52, such that distal opening 42 of lumen 50 is proximal of distal opening 44 of lumen 52. This particular embodiment advantageously minimizes the profile of sheath 40.

METHODS

Methods of using the embolic filter system of the present invention will now be described in the context of an interventional therapeutic procedure, such as

angioplasty, atherectomy, thrombectomy, stent placement or interventional diagnostic procedure, to treat and/or diagnose a lesion within a body lumen.

Figures 3A-3F illustrate the rapid exchange of embolic filters using an embodiment of the present invention. In practicing the subject invention, a generic guide wire (not shown) is manipulated into position in vessel V using well known percutaneous techniques. Once the generic guide wire is positioned, a multiple lumen delivery and retrieval sheath, such as the multiple lumen delivery and retrieval sheath 40 of Figure 2A, may be tracked over the generic guide wire to guide the delivery and retrieval sheath within the vasculature, e.g., lumen 50 may be used to track over the generic guide wire. Once delivery and retrieval sheath 40 is maneuvered into a position within vessel V distal lesion 4, the generic guide wire may be removed from the vasculature. In certain embodiments, positioning of the delivery and retrieval sheath 40 may be based on the position of a radiopaque marker or the like under fluoroscopy.

As shown in Figure 3A, first embolic filter, such as embolic filter 30 of Figure 1, is disposed within a lumen of delivery and retrieval sheath 40, for example first lumen 52 of delivery and retrieval sheath 40, and is operatively coupled to guide wire 38. Figure 3A shows embolic filter 30 in its constricted, undeployed, pre-delivery state within lumen 52. Thus, delivery and retrieval sheath 40, with embolic filter 30 disposed therein, is advanced through the vessel over a generic guide wire to a site distal to lesion 4. Once delivery and retrieval sheath 40 is at the desired location distal lesion 4, the generic guide wire can be removed from the vasculature.

Once the delivery and retrieval sheath 40 is appropriately positioned, guide wire 38 is held stationary while delivery and retrieval sheath 40 is retracted proximally to deploy embolic filter 30. Alternatively, delivery and retrieval sheath 40 may be held stationary while guide wire 38 is advanced distally. In either case, when embolic filter 30 is liberated from distal opening 42 of lumen 52 and is thus no longer confined to the delivery and retrieval sheath 40, support hoop 31 is expanded, as illustrated in Figure 3B. Subsequent to filter deployment, delivery and retrieval sheath 40 is removed from the vasculature. Figure 3B shows embolic filter 30 in its fully deployed state in vessel V, with support hoop 31 expanded to form an opening or mouth through which emboli and debris can flow into blood permeable sac 33.

After deployment of embolic filter 30 and subsequent removal of delivery and retrieval sheath 40, other interventional instruments, such as angioplasty catheters, atherectomy devices or stent delivery systems may be advanced along guide wire 38 to a position proximal of embolic filter 30. Thus, embolic filter 30 is positioned to trap emboli generated from the use of the interventional device on the lesion, e.g., pieces of plaque dislodged from the wall of vessel V by the interventional procedure.

With respect to Figures 3C-3E, the exchange of first embolic filter 30 for a second embolic filter is shown. Accordingly, when first embolic filter 30 becomes full of emboli E, it is removed from the vasculature to prevent injury to the patient. If it is desirable to proceed with the interventional procedure, the first embolic filter may be exchanged for a second embolic filter. As such, the interventional device (not shown) is first removed from the vasculature by tracking it proximally over guide wire 38. Delivery and retrieval sheath 40 is again advanced over guide wire 38 to a site distal to lesion 4 and proximal to the now occluded first embolic filter 30. As illustrated in Figure 3C, a second embolic filter assembly 64, including second embolic filter 60, support hoop 62 and suspension strut 66, is operatively coupled to guide wire 70 in second lumen 50 of delivery sheath 40 with second embolic filter 60 in a contracted or undeployed, pre-delivery state.

In Figure 3D, once delivery and retrieval sheath 40 containing second embolic filter assembly 64 is advanced to the vicinity of first embolic filter 30, first embolic filter 30 is at least partially withdrawn proximally into first lumen 52 of delivery sheath 40. Alternatively, delivery sheath 40 can be advanced distally, at least partially over first embolic filter 30. In either case, the filter opening or mouth of first embolic filter 30 essentially closes or collapses such that emboli disposed in blood permeable sac 33 of first embolic filter 30 is effectively retained inside the sac 33.

Referring now to Figure 3E, once first embolic filter 30 is withdrawn at least partially into first lumen 52 to seal the contents therein, guide wire 70 is held stationary while delivery and retrieval sheath 40 with first embolic filter 30 are retracted proximally or, alternatively, delivery and retrieval sheath 40 with first embolic filter 30 may be held stationary while guide wire 70 is advanced distally. In either case, when second embolic filter 60 is liberated from distal opening 44 of second lumen 50 and is thus no longer confined to delivery and retrieval sheath 40,

support hoop 62 is expanded. Once second embolic filter 60 is deployed in vessel V, delivery and retrieval sheath 40 along with first embolic filter 30 are removed from the vasculature. Figure 3F shows second embolic filter 60 in its fully deployed state in vessel V, with support hoop 62 expanded to form an opening or mouth through which emboli and debris can flow into blood permeable sac 64. As such, an interventional device can be again guided to lesion 4 to continue the interventional procedure.

In certain embodiments, more than two embolic filters may be advanced, deployed and retrieved through multiple lumen delivery and retrieval sheath 40. As such, these additional embolic filters may be advanced, deployed and retrieved through additional lumens of a multiple lumen delivery and retrieval sheath. For example, a third embolic filter may be advanced, deployed and retrieved through a multiple lumen delivery and retrieval sheath defining three lumens. Alternatively, the additional filters may be advanced, deployed and retrieved through the same lumen as that which was used to advance, deploy and retrieve the first embolic filter. For example, a third embolic filter may be advanced, deployed and retrieved through first lumen 52 of multiple lumen delivery and retrieval sheaths 40 or 130 after the first embolic filter 30 has been withdrawn and removed therefrom. In either case, additional embolic filters may be advanced, deployed and removed as described above.

EXCHANGE SHEATHS

Figs. 4A-4D illustrate a filter exchange system in accordance with a particular embodiment of the present invention. As shown in Fig. 4A, a guide wire 104 is inserted into vessel V and extends distally of a lesion 4. Guide wire 102 has a proximal end 170, a distal end 168, and a distal tip region 104.

As illustrated in Fig. 4B, a guide tip 150 defining a guide wire lumen 168 is advanced to a distal end 168 of guide wire 102. Guide tip 150 has a tapered profile, with a larger diameter portion on proximal end 152, and a smaller diameter portion on distal end 151. Guide tip 150 can be made from, for example, a relatively soft atraumatic polymer or a radiopaque coil. A filter sheath 154 defines a filter lumen 172 containing a filter assembly 174 therein. Disposed in part within filter lumen 172

is a filter wire 138 having a proximal end and a distal end 156. Distal end 156 of filter wire 138, in turn, is attached to the proximal end of guide tip 150 at flange 176. Filter wire 138 can be attached to guide tip 150 at flange 176 by, for example, molding tip 150 over flange 176. Alternatively, filter wire 138 can be attached to guide wire shaft 150 by means of a shrink-fit, adhesive, interference fit or other means.

In use, guide tip 150, operatively coupled to filter sheath 154 and filter assembly 174, can be advanced over guide wire 102 to a point within the vessel V distal lesion 4. As shown in Fig. 4B, embolic filter 133 is housed within filter lumen 172 in its un-deployed, collapsed state. Once filter assembly 174 is advanced distally of lesion 4 to a desired location within vessel V, guide wire 102 can be removed from guide tip 150, as illustrated in Fig. 4C. When filter assembly 174 is appropriately positioned, filter wire 138 is held stationary while filter sheath 154 is retracted proximally, allowing embolic filter 133 to deploy in the vessel. Alternatively, filter sheath 154 can be held stationary while filter wire 138 is advanced distally. In either case, when embolic filter 133 is removed from filter sheath 154 and thus no longer confined within filter lumen 172, embolic filter 133 can be fully deployed.

Fig. 4D illustrates filter assembly 158 in a deployed state after the removal of filter sheath 154. As shown in Fig. 4D, filter assembly 158 having an embolic filter 133, support hoop 136, suspension strut 162 and filter sac 180 is shown fully deployed at a point distal lesion 4. Suspension strut 162 is connected to support hoop 136 at its distal end, and to joint 140 at its proximal end. The proximal end of suspension strut 162 is attached to filter wire 138 by means of a solder bead or other attachment means. Alternatively, joint 140 can be a tube to allow rotation of guidewire 138. When the therapeutic procedure is completed, filter 133 can be retracted back into filter sheath 154 or other retrieval catheter and removed from the vessel. Alternatively, filter assembly 158 can be retracted back into filter sheath 154, or other retrieval catheter, by pulling filter guide wire 138 proximally until embolic filter 133 is encased in part with filter lumen 172. Although the filter assembly shown in Figs. 4A-D is similar to the filter assembly discussed *infra* in Fig. 1, other embolic filters can be employed by the filter exchange system of Figs. 4A-4D without departing from the scope of the subject invention.

Fig. 5A is an alternative embodiment of an exchange sheath in accordance with the present invention. As illustrated in Fig. 5A, filter assembly 30 is disposed along a filter guide wire 38 in an exchange sheath 100. Sheath 100 has a proximal end (not shown) and a distal end. Exchange sheath 100 further includes a filter sheath 106 defining a filter lumen. Filter sheath 106 includes a shaft 108 and a larger diameter portion 110 at the distal end of shaft 108. Larger diameter portion 110 at least in part contains filter 30 when filter guide wire 38 is disposed within the lumen of filter sheath 106.

Exchange sheath 100 also includes a guide wire sheath 112. As shown in Fig. 5A, guide wire sheath 112 can be substantially shorter than exchange sheath 100. Guide wire sheath 112 includes a guide wire lumen therethrough. In one advantageous embodiment, guide wire lumen 112 is discontinuous, and includes a skived portion 114 adjacent the larger diameter portion 110 of filter sheath 106. This can be done to reduce the profile of exchange sheath 100 at larger diameter portion 110. Moreover, a guide wire 102 having a distal spring tip 104 can be disposed within the guide wire lumen of sheath 112. Once the exchange sheath 100 containing collapsed and un-deployed embolic filter 30 is advanced along guide wire 102 to a portion of the vessel distal lesion 4, guide wire 102 can be removed from the vessel. Alternatively, embolic filter 30 can be first advanced along filter wire 38 distally until it is fully deployed within the vessel, at which point guide wire 102 can be removed from the vessel.

Fig. 5B illustrates the exchange sheath 100 in Fig. 5A subsequent to removal of the guide wire 102 from vessel V, but prior to deployment of embolic filter 30. As shown in Fig. 5B, once filter containing region 110 and filter 30 have been advanced distally of the lesion, and once guide wire 102 is withdrawn from the vessel, embolic filter 30 can be deployed within the vessel by either holding the filter wire 38 static and sliding shaft 108 proximally, or alternatively, by holding shaft 108 static and sliding the filter wire 38 distally. Once filter assembly 29 is disposed in vessel V, as shown in Fig. 5C, various devices such as angioplasty catheters or atherectomy catheters can be advanced over filter wire 38 to lesion 4.

During angioplasty, atherectomy or other procedures, emboli can break free from lesion 4 and drift into filter sac 33. Emboli might eventually substantially fill

filter sac 33, in whole or in part occluding vessel V. Embolic filter 30 can then be removed from vessel V by first removing the angioplasty catheter, atherectomy catheter or other device. Then, as shown in Fig. 5D, exchange sheath 100 and guide wire 102 can be advanced over filter wire 38. Filter 30 can then at least in part be collapsed and withdrawn from vessel V by drawing said filter into filter sheath 106, or advancing exchange sheath 100 including filter sheath 106 at least in part over embolic filter 30. Once filter 30 is at least in part in exchange sheath 100, filter assembly 29 and exchange sheath 100 can be removed proximally from vessel V over guide wire 102. Guide wire 102 is then left in place across the lesion. Another filter assembly 29 can then be placed in vessel V by repeating the steps described above beginning with Fig. 5A.

KITS

Also provided by the subject invention are kits for use in practicing the subject methods. A kit of the subject invention includes at least one embolic filter assembly and at least one multiple lumen delivery and retrieval sheath, as described above. Other kits may include one or more embolic filter assemblies without the accompanying multiple lumen delivery and retrieval sheath. Certain kits may include one or more vascular interventional systems, such as an angioplasty system, a stent placement system, an atherectomy system, an embolectomy system and a diagnostic system in addition to a subject embolic filter assembly and/or multiple lumen delivery and retrieval sheath. Finally, the subject kits preferably include instructions for using the subject device(s) and system(s) during an interventional procedure to protect the patient against emboli. These instructions may be present in one or more of the instructions for use included in the kits, packaging, label inserts or containers present in the kits, and the like.

It is evident from the above description that the subject inventions provide a significant contribution to the field of embolic protection. It is recognized that departures from the described embodiments may be made which are within the scope of the invention, and that obvious modifications will occur to one skilled in the art upon reading this disclosure. Such departures and modifications that come within the

meaning and range of equivalents of the disclosed concepts are intended to be included within the scope of the appended claims.

WHAT IS CLAIMED:

1. A system for rapidly exchanging embolic filters within a vessel, the system comprising:
 - a first embolic filter coupled to a first guide wire;
 - a second embolic filter coupled to a second guide wire; and
 - a multiple lumen delivery and retrieval sheath having multiple lumens, wherein said first and second embolic filters are translatable through said multiple lumens.
2. The system of claim 1, wherein each of said embolic filters comprises a blood permeable sac having an opening, whereby emboli enter said embolic filter through said opening and become entrapped within said blood permeable sac.
3. The system of claim 2, wherein each of said embolic filters further comprises a support hoop which forms a mouth or proximal opening of said blood permeable sac.
4. The system of claim 3, wherein said support hoop is self-expanding.
5. The system of claim 4, wherein said support hoop has a preformed shape.
6. The system of claim 5, wherein said support hoop is composed of nitinol.
7. The system of claim 3, wherein said support hoop is mounted on a suspension strut, whereby said suspension strut is attached to said guide wire at a location proximal to said support hoop.
8. The system of claim 1, wherein each of said multiple lumens has an inner wall and an outer wall.

9. The system of claim 8, wherein each of said inner walls is coated with a hydrophilic coating.
10. The system of claim 8, wherein each of said outer walls is coated with a hydrophilic coating.
11. The system of claim 1, wherein said multiple lumen delivery and retrieval sheath is comprised of at least two lumens.
12. The system of claim 11, wherein said at least two lumens are dimensioned such that when disposed therein, said embolic filters are restrained in a low profile position.
13. The system of claim 11, wherein said at least two lumens are dimensioned such that said embolic filters, when filled with emboli, may be at least partially withdrawn in said lumens such that emboli contained in said embolic filters is retained therein.
14. The system of claim 11, wherein the distal ends of said at least two lumens terminate at substantially the same point.
15. The system of claim 11, wherein the distal end of at least one of said at least two lumens terminates proximally of the distal end of at least one other of said at least two lumens.
16. The system of claim 1, wherein said delivery and retrieval sheath is comprised of at least three lumens.

17. The system of claim 16, wherein at least one lumen of said at least three lumens is so dimensioned such that an interventional therapeutic or diagnostic device and/or a stent can be advanced therethrough.

18. The system of claim 16, wherein the distal end of at least one of said at least three lumens terminates proximally of the distal ends of at least two other of said at least three lumens.

19. The system of claim 1, wherein said multiple lumen delivery and retrieval sheath is further comprised of a radiopaque material.

20. The system of claim 19, wherein said radiopaque material is selected from the group consisting of a platinum coil, platinum band, platinum marker and barium sulfate.

21. A method of rapidly exchanging embolic filters in a vessel, comprising the steps of:

- providing a multiple lumen delivery and retrieval sheath having a first embolic filter coupled to a first guide wire disposed within a first lumen;
- advancing said multiple lumen delivery and retrieval sheath to a target site within a vessel;
- deploying said first embolic filter within said vessel;
- collecting emboli in said first embolic filter;
- advancing a second embolic filter coupled to a second guide wire through a second lumen of said multiple lumen delivery and retrieval sheath; and
- exchanging said first embolic filter with said second embolic filter within the vessel.

22. The method of claim 21, wherein said exchanging comprises withdrawing said first embolic filter at least partially into said first lumen and deploying said second embolic filter within said vessel.

23. The method of claim 21, further comprising the steps of collecting emboli in said second embolic filter and withdrawing said second embolic filter at least partially into said second lumen.

24. The method of claim 21, further comprising advancing a third embolic filter through said multiple lumen delivery and retrieval sheath.

25. The method of claim 24, wherein said third embolic filter is advanced through a third lumen.

26. The method of claim 24, wherein said third embolic filter is advanced through said first lumen.

27. The method of claim 24, further comprising deploying said third embolic filter in said vessel.

28. The method of claim 23, further comprising the step of withdrawing said multiple lumen delivery and retrieval sheath from said vasculature.

29. The method of claim 21, further comprising advancing an interventional therapeutic or diagnostic device and/or a stent to the site of the stenosis to perform an interventional procedure thereon.

30. The method of claim 29, whereby said interventional therapeutic or diagnostic device and/or a stent is advanced to said stenosis through a third lumen of said delivery and retrieval sheath.

31. The method of claim 30, further comprising performing an interventional procedure within said vessel.

32. The method of claim 31, whereby said interventional procedure is performed with said multiple lumen delivery and retrieval sheath in the vasculature.

33. A kit for rapidly exchanging embolic filters within a vessel, comprising:
at least one embolic filter assembly, wherein said embolic filter assembly comprises an embolic filter operatively coupled to a guide wire; and
and at least one multiple lumen delivery and retrieval sheath.

34. The kit of claim 33, further comprising one or more vascular interventional systems.

35. The kit of claim 34, wherein said one or more vascular interventional systems are selected from the group consisting of an angioplasty system, a stent placement system, an atherectomy system, an embolectomy system and a diagnostic system.

36. A filter exchange system, comprising:
an elongate shaft having a proximal end and a distal end, the shaft defining a guide wire lumen and a filter lumen;
a filter assembly including an elongate shaft having a proximal end and a distal end; and
a filter disposed on a filter assembly; wherein the filter assembly is disposed at least in part within the filter lumen.

37. The system in accordance with claim 36, wherein the guide wire lumen is substantially shorter than the filter lumen.

38. The system in accordance with claim 36, wherein the filter lumen has a proximal end and a distal end, the distal end of the filter lumen includes a filter containing region.

39. The system in accordance with claim 38, wherein the filter is disposed within the filter containing region.

40. The system in accordance with claim 38, wherein the guide wire lumen is disposed proximally and distally of the filter containing regions, the filter containing region has a larger luminal diameter than an alternate portion of the filter lumen; and the guide wire lumen is at least in part discontinuous at the filter containing region.

41. The system in accordance with claim 36, wherein a guide wire is disposed in a guide wire lumen.

42. A filter exchange system, comprising:
a guide tip having a proximal end and a distal end, said guide tip defining a guide wire lumen therethrough;
a filter wire having a proximal end and a distal end, said guide tip attached at the distal end of said filter wire; and
a filter assembly disposed along the filter wire distally of the guide tip.

43. The filter exchange system in accordance with claim 42, wherein the guide tip has a tapered profile.

44. The filter exchange system in accordance with claim 42, wherein the guide tip has a tapered profile having a larger diameter portion at the proximal end, and a smaller diameter portion at the distal end.

45. The filter exchange system in accordance with claim 42, wherein said filter assembly includes a support hoop connected to a filter, a filter sac and a suspension strut.

46. The filter exchange system in accordance with claim 45, wherein said suspension strut is attached to a portion of the filter wire.

47. The filter exchange system in accordance with claim 42, wherein a guide wire is disposable in the guide wire lumen.

48. The method of exchanging the guidewire with a filter wire assembly, comprising the steps of:
placing a guidewire in a vessel at a target site;
providing a filter wire assembly, having a proximal end and a distal end, a filter disposed proximate the distal end, and a portion of the filter wire assembly defining a guidewire lumen;
placing the guidewire within the guidewire lumen;
advancing the filter assembly distally into the vessel to the target site; and
removing the guidewire distally from the target site.

49. The method in accordance with claim 48, wherein the guidewire lumen is disposed distally of the filter.

50. The method of removing a filter while maintaining wire access, comprising the steps of:
providing a multiple lumen sheath having a filter coupled to a first wire disposed within a first lumen, and a second wire disposed in a second lumen, and the filter being disposed at a target site within a vessel;
advancing the multiple lumen sheath to the target site;
placing the filter into the first lumen; and
removing the filter from the target site.

51. The method in accordance with claim 50, further comprising the step of placing the second wire at the target site.

52. The method in accordance with claim 51, wherein the second wire is placed at the target site prior to removing the filter from the target site.

Fig. 1

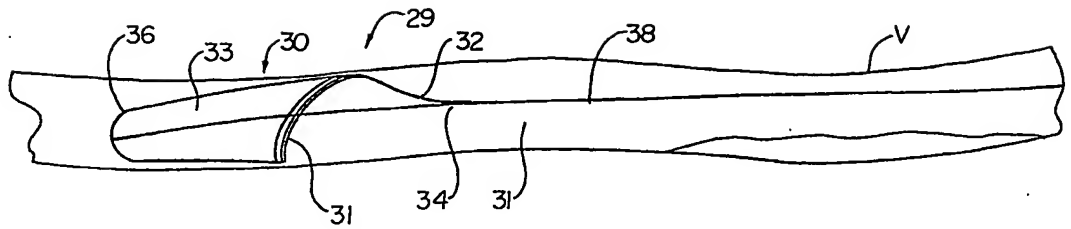


Fig. 2A

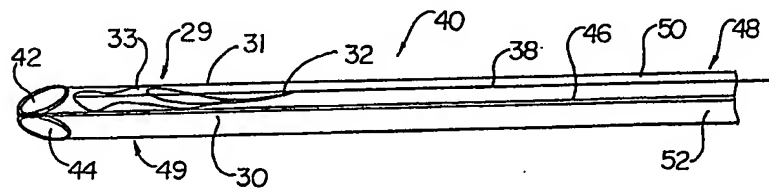
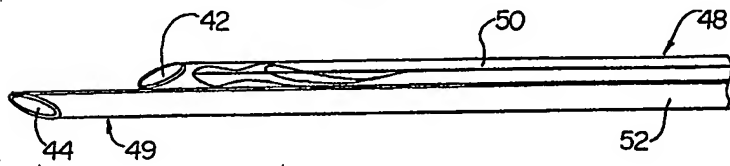


Fig. 2B



217

Fig. 3A

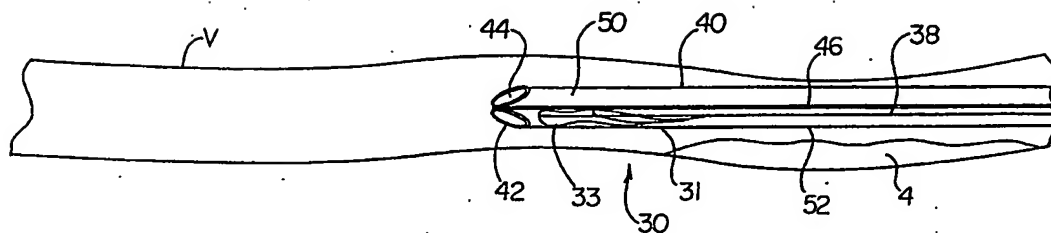


Fig. 3B

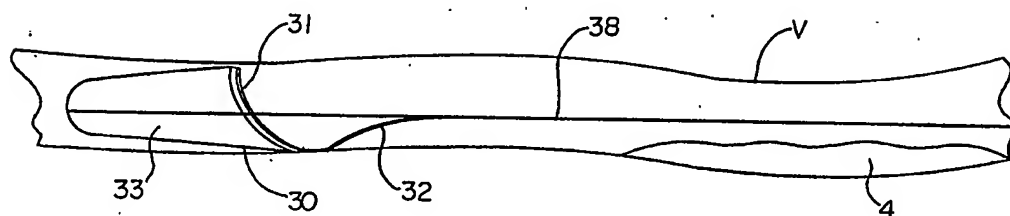
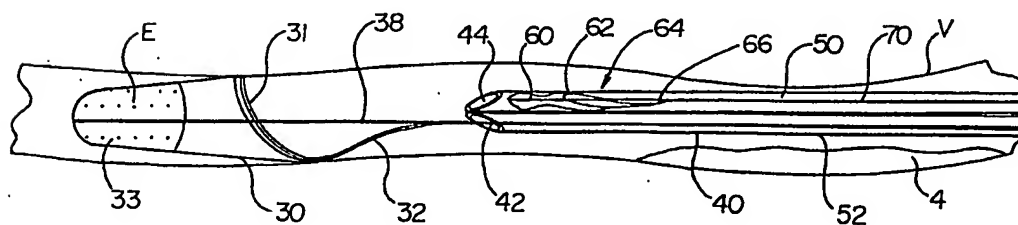


Fig. 3C



3/7

Fig. 3D

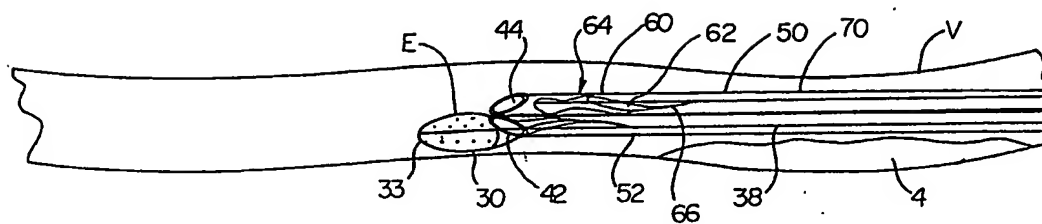


Fig. 3E

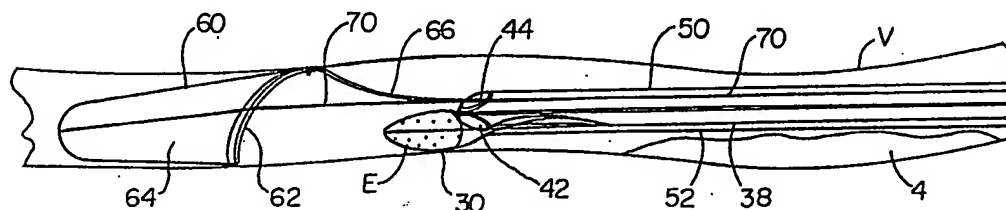


Fig. 3F

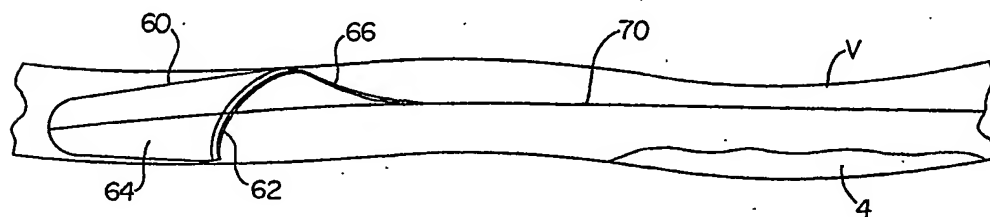


Fig. 4A

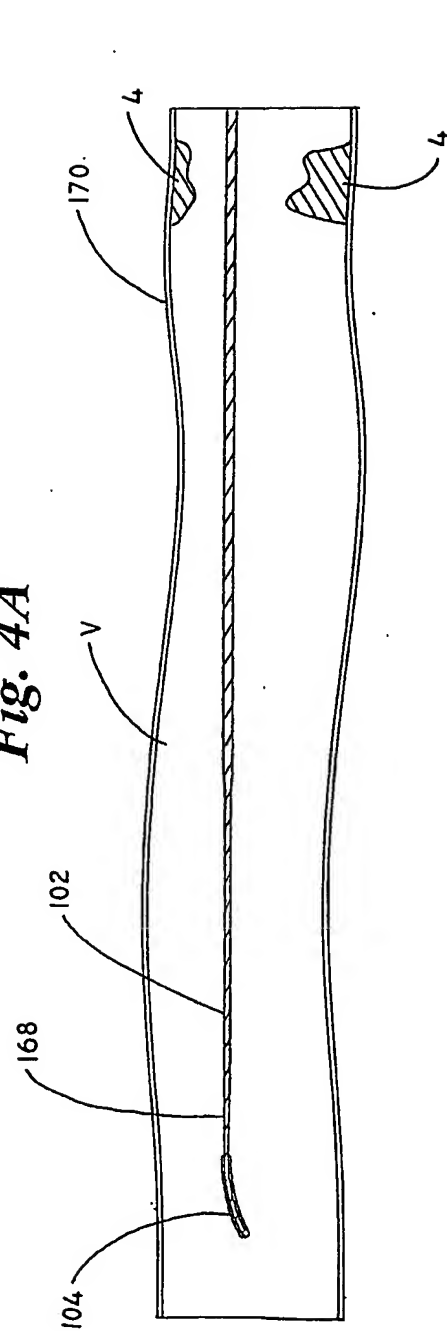


Fig. 4B

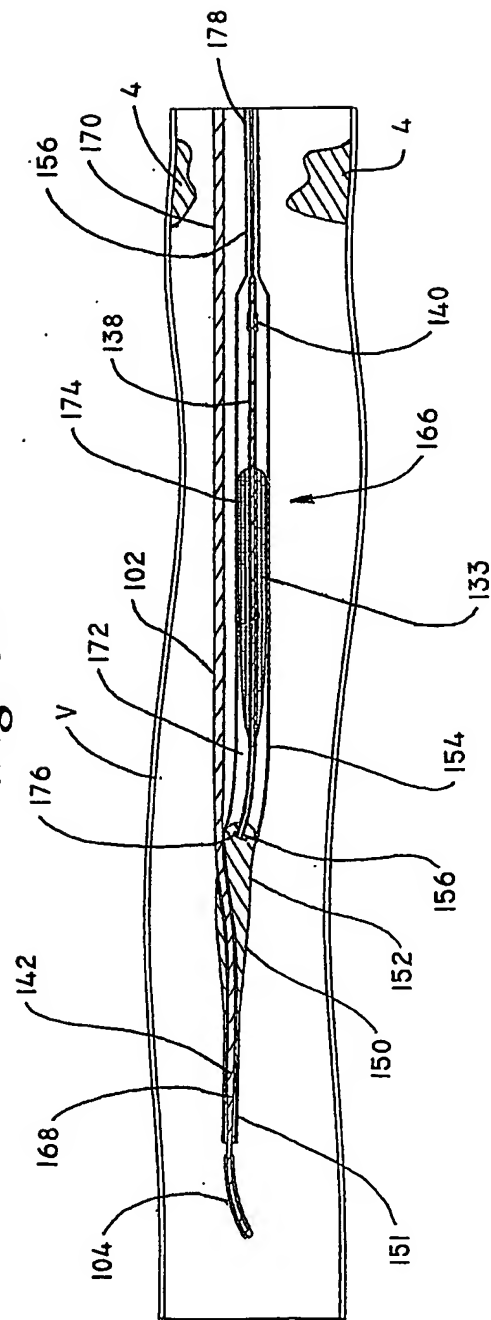


Fig. 4C

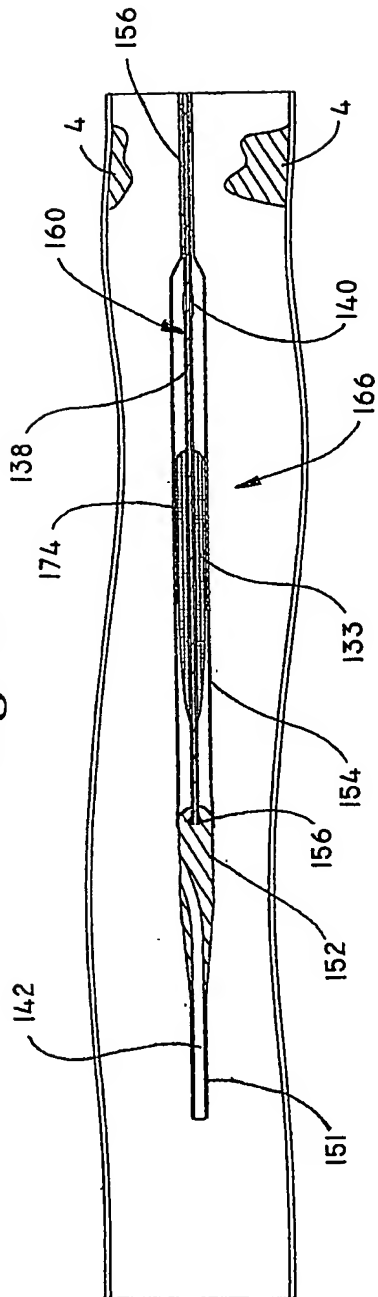
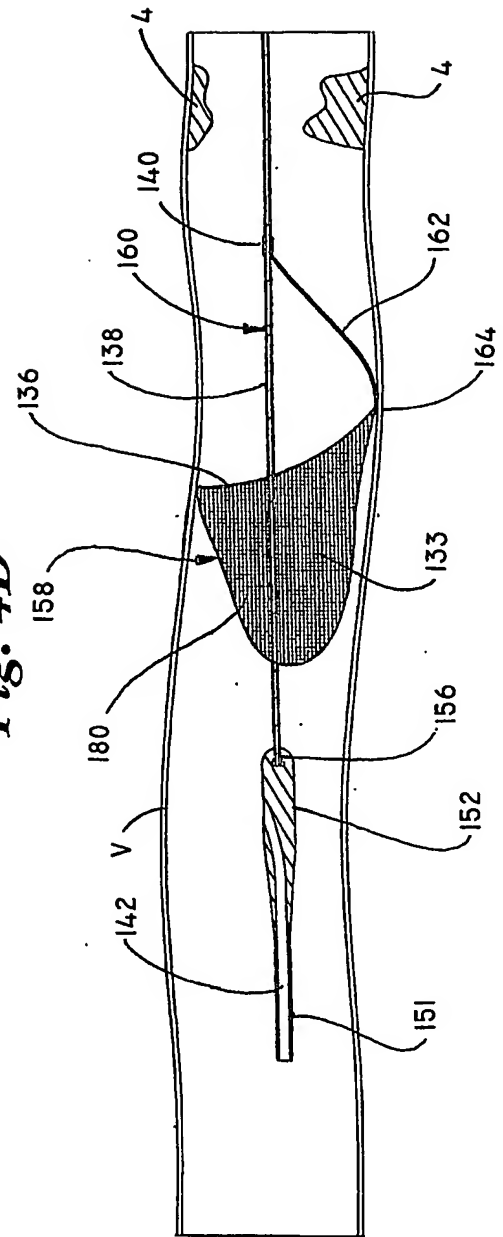


Fig. 4D



6/7

Fig. 5A

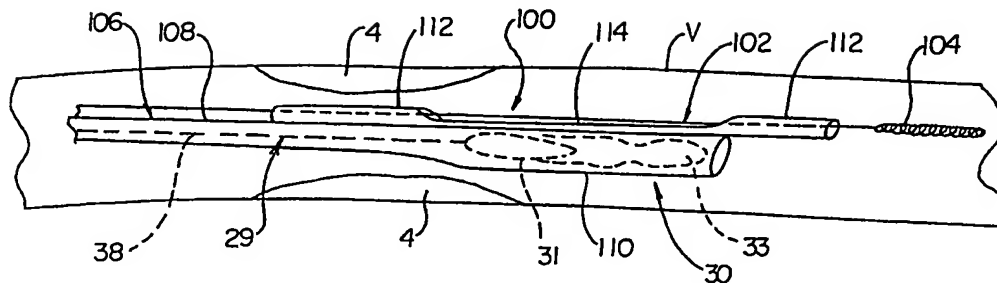


Fig. 5B

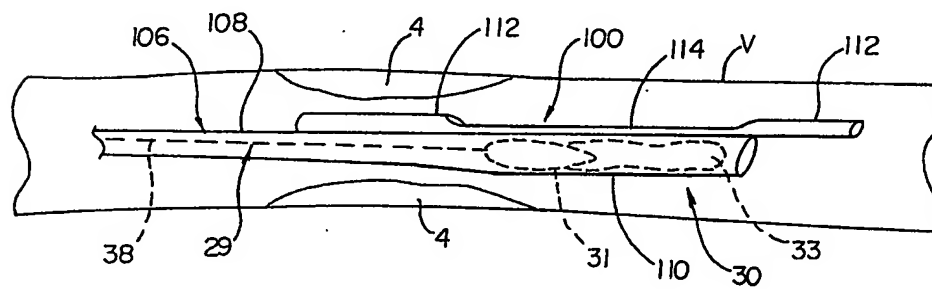


Fig. 5C

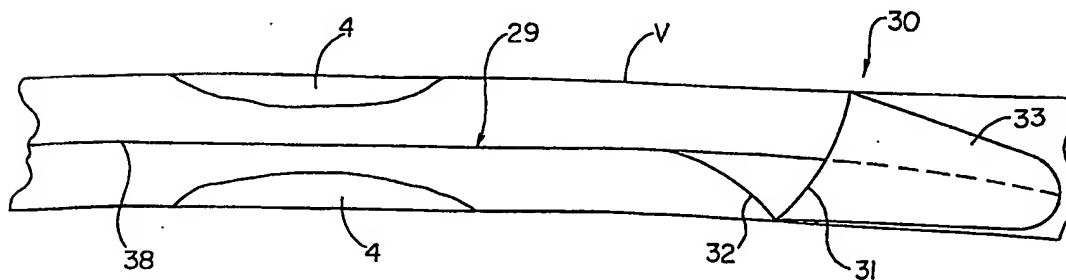
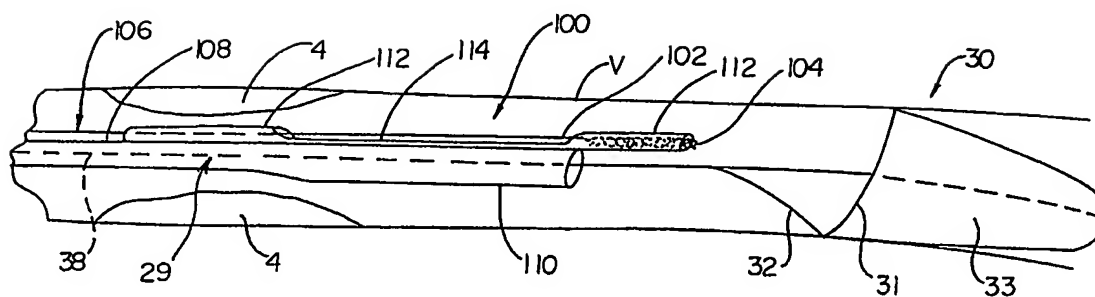
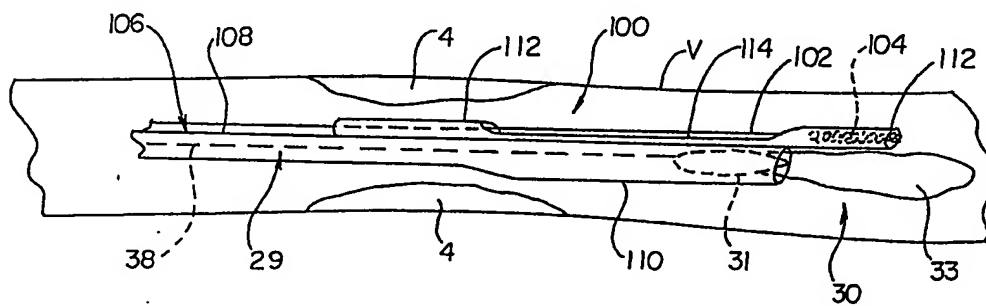


Fig. 5D**Fig. 5E**

INTERNATIONAL SEARCH REPORT

National Application No

PCT/US 02/30114

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01 08743 A (INCEPT LLC) 8 February 2001 (2001-02-08) the whole document	1-8, 11-14, 19,20, 33-36, 38,41, 42,45,47
X	US 6 142 987 A (TSUGITA ROSS S) 7 November 2000 (2000-11-07) column 5, line 48 - line 62; figures 1G,1K	33-39,41
X	WO 00 76390 A (ARTERIA MEDICAL SCIENCE INC) 21 December 2000 (2000-12-21) page 20, line 3 -page 21, line 6; figures -/--	33-35

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

13 January 2003

Date of mailing of the international search report

20/01/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3018

Authorized officer

Neumann, E

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/30114

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	US 2002/095141 A1 (BELEF W MARTIN ET AL) 18 July 2002 (2002-07-18) paragraph '0053!; figures -----	36-39, 41,42
P,X	WO 02 054988 A (MEDTRONIC AVE INC) 18 July 2002 (2002-07-18) page 8, line 6 - line 31; figures -----	33-35
A	WO 01 67989 A (BESSELINK PETER ;DON MICHAEL T ANTHONY (US)) 20 September 2001 (2001-09-20) paragraph '0093! - paragraph '0096!; claims 3-7; figures -----	1,33-36, 42

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-20

A system comprising first and second filters, each coupled to a guide wire and a sheath having multiple lumens wherein the filters are translatable through the lumens

2. Claims: 33-35

A kit comprising a filter coupled to a guide wire and a multiple lumen sheath

3. Claims: 36-41

A filter exchange system comprising a shaft having a guide wire lumen and a filter lumen, a filter assembly having an elongate shaft and a filter wherein the assembly is disposed within the filter lumen

4. Claims: 42-47

A filter exchange system comprising a guide tip defining a guide wire lumen, a filter wire and a filter assembly

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/30114

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 21-32, 48-52
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/30114

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0108743	A	08-02-2001	US 6348062 B1	19-02-2002
			US 6203561 B1	20-03-2001
			US 6214026 B1	10-04-2001
			US 6179861 B1	30-01-2001
			US 6129739 A	10-10-2000
			AU 6391700 A	19-02-2001
			AU 6614900 A	19-02-2001
			EP 1244492 A1	02-10-2002
			EP 1207933 A1	29-05-2002
			WO 0108742 A1	08-02-2001
			WO 0108743 A1	08-02-2001
			US 2002133191 A1	19-09-2002
			US 2002161393 A1	31-10-2002
			US 6371970 B1	16-04-2002
			US 2002022858 A1	21-02-2002
			US 2002026211 A1	28-02-2002
US 6142987	A	07-11-2000	CA 2345654 A1	08-02-2001
			DE 1117343 T1	13-06-2002
			EP 1117343 A1	25-07-2001
			WO 0108596 A1	08-02-2001
WO 0076390	A	21-12-2000	US 6206868 B1	27-03-2001
			US 2001044598 A1	22-11-2001
			AU 5738900 A	02-01-2001
			EP 1210142 A2	05-06-2002
			WO 0076390 A2	21-12-2000
			US 2002151922 A1	17-10-2002
			US 2002173815 A1	21-11-2002
			US 2002107479 A1	08-08-2002
			US 2002022859 A1	21-02-2002
US 2002095141	A1	18-07-2002	US 2002087119 A1	04-07-2002
			WO 02062266 A2	15-08-2002
WO 02054988	A	18-07-2002	US 2002004667 A1	10-01-2002
			WO 02054988 A2	18-07-2002
WO 0167989	A	20-09-2001	AU 4915301 A	24-09-2001
			EP 1253871 A2	06-11-2002
			WO 0167989 A2	20-09-2001
			US 2001044634 A1	22-11-2001